UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 02-11738-RWZ

UNITED STATES, ex. rel. CONSTANCE A. CONRAD

v.

HEALTHPOINT, LTD.

MEMORANDUM OF DECISION

March 26, 2012

ZOBEL, D.J.

On August 29, 2002, Constance A. Conrad brought an action on behalf of the United States, as relator pursuant to the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730(b)(1), against a number of pharmaceutical manufacturers and distributers for receiving federal Medicaid and Medicare payments for drug products that allegedly had never been approved by the U.S. Food and Drug Administration ("FDA") and/or eligible for reimbursement (Docket # 1). Stemming from the investigation conducted in response to the complaint, on March 31, 2011, the United States brought this separate three-count complaint against Healthpoint, Ltd., a Texas-based pharmaceutical manufacturer, alleging it violated the FCA and was unjustly enriched by submitting Medicare and Medicaid reimbursement claims, from 2002 to 2006, for a drug named "Xenederm," a topical ointment used to promote the healing and treatment of ulcers and wounds, despite the fact that the drug was

ineligible for reimbursement. Defendant has moved to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim.

I. Background

It is unnecessary to fully recount the lengthy and complex regulatory history for marketing and approval of new drugs in the United States that the parties have diligently outlined; suffice it to say, Congress did not mandate that drugs marketed prior to 1938 be proven safe or effective. Then beginning in 1938, the Food, Drug and Cosmetic Act ("FDCA") (Pub. L. No. 75-717, 52 Stat. 1040 (1938)) required manufacturers to submit to the FDA a new drug application ("NDA") demonstrating that a drug was safe ("safety-only NDA drug"). In 1962, a further amendment to the FDCA demanded that new drugs be proven both safe and effective before they could be marketed (21 U.S.C. § 355(b)(1)(A)).

Following the 1962 amendment, the FDA, with assistance from the National Academy of Sciences/National Research Council ("NAS/NRC"), reviewed the safety-only NDA drugs for effectiveness and published its conclusions in the Federal Register. This process was known as the Drug Efficacy Study Implementation ("DESI") program. Id. If DESI review of a drug concluded that the drug was "less than effective" ("LTE") for some or all of its indications, any interested party could challenge the determination. If no one challenged the FDA's determination, or if the challenge was unsuccessful, approval for the drug was rescinded.

In April 2002 defendant began marketing Xenederm, a topical ointment indicated to "promote the healing and treatment of decubitus ulcers, varicose ulcers, and

dehiscent wounds." Docket # 217 at ¶ 47. At no time before its introduction of the drug did defendant complete any clinical studies to establish the safety and effectiveness pursuant to FDA standards. Instead, it modeled Xenederm after "Granulex," a drug introduced to the market prior to 1962, and not reviewed under DESI, which contained the same active ingredients and was indicated to treat the same ailments as Xenederm. Xenederm's and Granulex's active ingredients are castor oil, balsam of Peru, and trypsin.

Drugs not approved by the FDA pursuant to safety-only NDAs, including drugs marketed prior to 1938 (e.g. Granulex) and products that were "identical, related or similar" to ("IRS") them (e.g., Xenederm), are not categorically precluded from Medicaid and Medicare reimbursement. However, if approval for a drug was rescinded under the DESI program, any drugs identical, related or similar to such rescinded drug (regardless of market entry date) are also rescinded and ineligible for Medicaid and Medicare reimbursement.

On June 25, 1970, the FDA evaluated "Parenzyme," a trypsin-containing prescription drug, and issued a notice in the Federal Register concluding that "[t]opical preparations containing trypsin, chymotrypsin, and aminacrine hydrochloride lack substantial evidence of effectiveness for labeled claims for anti-infective and debriding actions on sloughing and necrotic or infected tissue associated with wounds, burns ... and ulcers (decubitus, diabetic, or varicosose)" (the "Parenzyme notice"). Id. at ¶ 39. Based upon this finding, the FDA withdrew its approval for Parenzyme in 1972. On July 26, 1976, the FDA evaluated "Tryptar," another prescription drug containing

trypsin, and issued a notice in the Federal Register announcing there was "lack of substantial evidence of effectiveness" for its use as a debriding agent (the "Tryptar notice"). Id. at ¶ 40.

The government alleges that Xenederm (which also contains trypsin indicated as a debriding agent) is identical, related or similar to Parenzyme and Tryptar and therefore that the Parenzyme and Tryptar notices rendered Xenederm LTE and ineligible for payment under Medicaid and Medicare. Consequently, Healthpoint's classification and coding of Xenederm as a drug eligible for reimbursement on quarterly statements submitted to the Centers for Medicare and Medicaid Services amounted to false claims under the FCA.

II. Standard

On a motion to dismiss, the "court takes as true all well-pleaded facts in the complaint[ ], scrutinize[s] them in the light most hospitable to the plaintiffs' theory of liability, and draw[s] all reasonable inferences therefrom in the plaintiffs' favor." Fothergill v. United States, 566 F.3d 248, 251 (1st Cir. 2009). The inquiry is limited to the facts alleged in the complaint, incorporated into the complaint, or susceptible to judicial notice. See In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 15 (1st Cir. 2003). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). Plausibility "is not akin to a probability requirement, but [requires] more than a sheer possibility ..." Id. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements

of a cause of action will not do.'" Id.

III. Analysis

The FCA imposes liability on any person who (1) "knowingly presents or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(1986); or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," Id. § 3729(a)(1)(B)(2009).[1] Under either provision, the government must establish, at a minimum, that Healthpoint knowingly made a false claim (including a false record or document) seeking reimbursement for Xenederm. The statute provides that the term knowingly does not require "proof of specific intent to defraud," but rather means that a person, "with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1986); id. § 3729(b)(1)(2009).

1. Defendant's Scienter

Defendant first argues that the government fails to adequately allege the requisite scienter to subject defendant to FCA liability. It contends that modeling Xenederm after Granulex was objectively reasonable. Defendant also claims it was

[1] The FCA was amended in 2009 pursuant to the Fraud Enforcement and Recovery Act (FERA) (2009 Acts. Pub.L. 111-21). The government asserts that § 3729(a)(1)(B)(2009), formerly § 3729(b)(1)(1986), is applicable to this case by virtue of § 4(f) of FERA which provides in subparagraph (B) that it "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act ... that are pending on or after that date", while § 3279(a)(1)(1986), under the unrevised act, remains applicable. Accordingly, the complaint includes two FCA counts, one pursuant to § 3729(b)(1)(1986) and the other pursuant to § 3729(a)(1)(B)(2009).

reasonable to rely on certain "lists" prepared by the FDA and made available in the 1980s after the Parenzyme and Tryptar notices issued, which notices categorized Granulex as a drug that "may or may not be subject to DESI as an identical, similar or related drug[ ]" and as a "non-DESI drug not reviewed as part of the original DESI project." Docket # 275 at 6-8. Finally, defendant says that it did not "know of the [Parenzyme and Tryptar notices]" and did not "know that the notices automatically applied to Xenederm." Id. at 4.

As an initial matter the several FDA lists and categorizations do not, a priori, establish that Granulex was eligible for reimbursement. The lists merely descriptively label Granulex as a drug "not reviewed under the original DESI program" but that nevertheless "may or may not be subject to DESI notices as an identical, similar or related drug [ ]." Docket # 275 at 6-8. In any event, Granulex was not reviewed under the DESI program, as that program applied solely to safety-only NDA drugs. Nevertheless, it was, as the FDA lists caution, subject to prior DESI notices by virtue of it being identical, related or similar to a drug that was reviewed. Moreover, even if the FDA's Granulex categorizations somehow bear on defendant's reasonableness, whether and to what extent defendant relied on them are issues of fact not properly resolved on a motion to dismiss.

2. Whether Parenzyme and Tryptar Notices Automatically Applied to Xenederm

Defendant also contends that the Parenzyme and Tryptar notices regarding trypsin do not automatically apply to and render ineligible for reimbursement

combination products containing trypsin and other active ingredients. It cites 21 C.F.R. § 310.6(b)(2), which states:

> Where experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs would conclude that the findings ... in a drug efficacy notice ... that a drug product is a "new drug" or [less than effective] ... are applicable to an [IRS] drug product, such product is affected by the notice. .. [A] combination drug product containing a drug that is [IRS] to a drug named in a notice may also be subject to the findings and conclusions in a notice that a drug product is a 'new drug' or [LTE].

Defendant asserts that, as a prerequisite to the FDA revoking its authority to market Xenederm, § 310.6(b)(2) entitles it to a finding from "experts qualified by scientific training" that Xenederm was subject to the prior Parenzyme and Tryptar notices. Far from requiring such a finding, § 310.6(b)(2) cautions that prior DESI notices may apply to Xenederm where experts "would conclude" they are applicable. What such experts would have concluded in 2002 when Xenederm was launched (or at any point thereafter) is not a matter properly decided on a motion to dismiss, nor is the asserted reasonableness and reliance thereon of defendant's interpretation of § 310.6(b)(2).

3. Fraud Pleading

More generally, defendant challenges the adequacy of the allegations of fraud.

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. This standard 'means that a complaint must specify 'the time, place, and content of an alleged false representation... The rule may be satisfied, however, where, although some questions

remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." U.S. ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (2009) (internal citations and quotations omitted); see U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.,579 F.3d 13, 29 (1st Cir. 2009) (finding Rule 9(b) met under the "flexible" Gagne test where "relators alleged submissions of false or fraudulent claims across a large cross-section of providers that alleges 'the who, what, where, and when of the allegedly false or fraudulent representations'") (internal citations omitted).

Here, the government alleges that between 2002 and 2006, Healthpoint, on quarterly statements submitted to the Centers for Medicare and Medicaid Services, recklessly coded Xenederm as eligible for reimbursement when in fact it was not. And it charges that these submissions were "material to the claims for government reimbursement for Xenederm." Docket # 217 at 70-71. These allegations adequately provide "the who, what, where, and when of the allegedly false claim" and satisfy the "flexible" Gagne formulation for pleading sufficiency in the FCA context. Duxbury, 579 F.3d at 29.

4. Unjust Enrichment

Finally, defendant asserts that the government's unjust enrichment count must be dismissed because Xenederm was eligible for Medicaid and Medicare reimbursement. However, this argument assumes in defendant's favor the very issue to be adjudicated. Whether Xenederm was in fact eligible for federal reimbursement during the period in question, and, in the event it was not, whether it would be unjust for defendant to retain the profits therefrom, remain entangled with disputed issues of facts

and determinations involving the reasonableness of Healthpoint's actions.

5. Conclusion

Defendant's motion to dismiss (Docket # 274) is DENIED. Defendant's motion to file reply (Docket # 294) is ALLOWED.

March 26, 2012
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE